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Adult patient access to electronic health records (Protocol)

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[Intervention Protocol]

Adult patient access to electronic health records

Elske Ammenwerth[1], Stefanie Lannig[2], Alexander Hörbst[1], Gerhard Muller[2], Petra Schnell-Inderst[3]

[1]Department of Biomedical Informatics and Mechatronics, UMIT - University for Health Sciences, Medical Informatics and Technology, Hall in Tirol, Austria. [2]Department of Nursing Science and Gerontology, UMIT - University for Health Sciences, Medical Informatics and Technology, Hall in Tirol, Austria. [3]Department of Public Health, Health Services Research and Health Technology Assessment, UMIT - University for Health Sciences, Medical Informatics and Technology, Hall in Tirol, Austria

Contact address: Elske Ammenwerth, Department of Biomedical Informatics and Mechatronics, UMIT - University for Health Sciences, Medical Informatics and Technology, Eduard Wallnöfer Zentrum 1, Hall in Tirol, 6060, Austria. elske.ammenwerth@umit.at.

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of providing access to electronic health records (EHR) alone or with additional functionalities to adult patients on a range of patient, patient-provider and health resource consumption outcomes.

The secondary objective is to compare the effects of providing EHR access alone, compared with EHR access with additional functionalities, to adult patients and to assess whether the effects differ among patient groups according to age, educational level or different status of disease (chronic or acute).

BACKGROUND

Description of the condition

This review will look at the effects of access to an institutional-based electronic health record (EHR) by adult patients irrespective of their diagnoses or the type of healthcare organization where they are treated.

Description of the intervention

The progress of modern information technology (IT) is changing and challenging health care. Health care depends strongly on the collection, storage, distribution and analysis of health-related information (Winter 2011). Health-related information concerning a specific patient is typically managed by EHR. An EHR is defined as the "electronic collection of health-related data relating to one subject of care, i.e. the patient" (Winter 2011). An EHR is maintained by a healthcare provider and provides healthcare professionals with real-time, patient-centred access to all health-related data relevant for patient care whenever and wherever it is needed.

Health-related data within an EHR comprise, among others, clinical assessments, laboratory results, radiology findings, nursing documentation, allergy information, medication information and discharge letters. These data are also called 'clinical data', as they are related to clinical care. However, an EHR may also contain general health-related data, such as data on lifestyle habits (e.g. eating, drinking, physical activity).

Patient-centred care has gained importance in both research and clinical practice (Scholl 2014). Patient-centred care may have positive effects on clinical outcomes (Rathert 2013). However, the concept of patient-centredness is not well defined and is based, among others, on concepts such as patient empowerment, patient participation or shared decision-making (Scholl 2014; Castro 2016).

Two important activities that foster patient-centred care are patient information (e.g. sharing information and knowledge between clinician and patient) and patient involvement in care (e.g. encouraging patients to participate actively in consultation and decision-making) (Scholl 2014). One precondition for both patient information and patient involvement is to give patients access to information about their clinical history and recent treatment. When the patient has access to this health-related data, it is expected that the patient may be better able to contribute to shared decision-making (Rigby 2015).

Thus, to facilitate patient-centred care, healthcare organizations have started to offer their patients access to the data that is stored on him or her in the institution-based EHR. The patient can access the data, read and print it, or download it and integrate it into any (electronic or paper-based) type of patient-held record (Ammenwerth 2012). This EHR access by the patient is typically web-based, allowing the patient to independently access this health-related data via the Internet from their home.

In addition to offering access to health-related data (called 'EHR access alone' in this protocol), a healthcare organization may offer further web-based services to the patient, including medication refill requests, appointment booking, secure messaging, personal health-related reminders, individual therapeutical recommendations, personal diaries and social networking with other patients. This is called 'EHR access with additional functionalities' in this protocol.

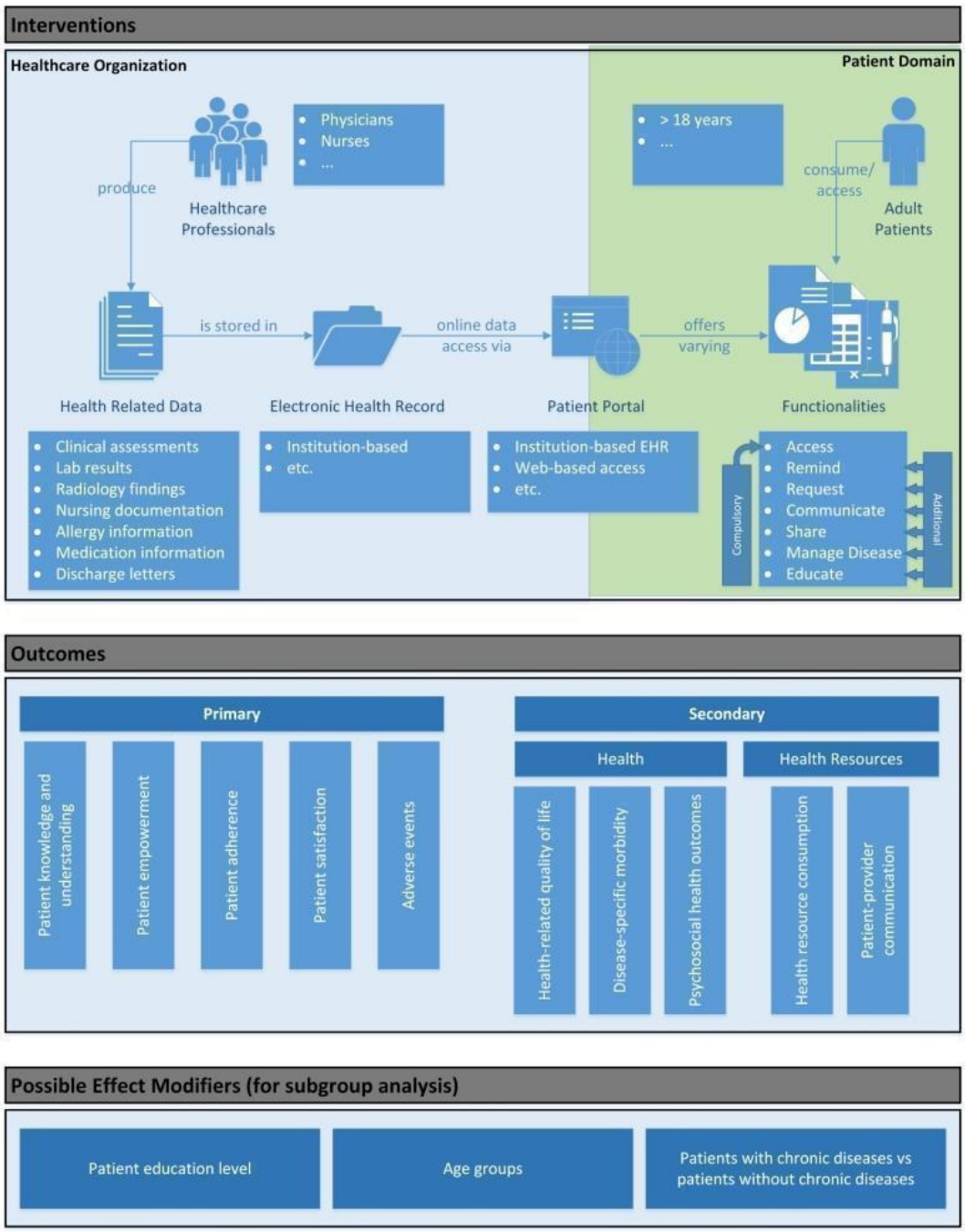
The interface providing EHR access (alone or with additional functionalities) is called a patient portal (Rigby 2015). A patient portal is defined as a web-based application allowing patients to access health-related data that is stored about them in the EHR of a healthcare provider. It may also offer additional functionalities, described in more detail below.

To allow a more specific description of the intervention, we will use the following list of typical functionalities: #1 denotes EHR access alone. #2 to #7 denote additional functionalities that may be offered to the patient in addition to EHR access alone. EHR access (#1) is the focus of the review; however, as EHR access is very often combined with additional functionalities, we will analyze all studies that include EHR access (#1) with or without additional functionalities (#2 to #7).

1. Access: access to health-related data (e.g. viewing test results, visit notes, information about condition or treatment, medical history) (this is the focus of this review).
2. Remind: preventive health maintenance reminders (e.g. for immunization, mammography, screening tests).
3. Request: transactional services (e.g. repeat prescription, appointment booking, referral requests).
4. Communicate: bilateral messaging service (e.g. secure messaging for non-urgent medical questions and administrative concerns).
5. Share: patient self-documentation (e.g. manage medication list, approve content of clinical notes, upload blood pressure measurements, personal diary).
6. Manage disease: individualized disease management functions (e.g. individual guidelines, generation of an individual care plan).
7. Educate: general educational health-related information.

See Figure 1 for a detailed description of the relationships between the healthcare organization, health-related data, EHR, patient portal and the additional functionalities that may be offered to and used by patients.

Figure 1. Logic model: healthcare organizations produce health-related data, store them in their institutional EHR and make them available to the patient through a patient portal. EHR access may be offered alone or in combination with additional functionalities.



An EHR providing access only, or with additional functionalities, may be provided to all patients of a given healthcare organization. It may also be provided to a specific group of patients such as those with diabetes mellitus or cancer.

EHR access with or without additional functionalities may also be offered to parents of children who are treated in a healthcare organization, or to relatives or other informal carers of patients who are unable to use EHR access themselves. In these cases, the target of the intervention is not the patient, but relatives or other informal carers, and a direct outcome (e.g. on patient empowerment) cannot be expected. For this review, we will focus on adult patients as users only, excluding those studies where relatives or informal carers are mentioned as major target group of the intervention.

Besides healthcare organizations, EHR access may also be offered on a national scale. Countries such as Austria, Denmark or Sweden have already started eHealth projects to make selected health-related data from various healthcare organizations available via the web to their citizens (Moen 2013). These national initiatives often focus on EHR access alone. We will include these in the review as the effects of these that combine health-related data from more than one healthcare organization may be quite different to those providing health-related data by a specific healthcare organization.

This protocol uses the term EHR (electronic health record) throughout to denote the electronic collection of health-related data to one subject of care, as defined above. In the literature, other terms may be used to refer to related concepts, such as electronic medical record (EMR) or personal health record (PHR). The World Health Organization (WHO) uses the following definition: "EMRs are in-house electronic versions of the traditional paper charts that collect, store and display patient information," and that "EHRs include additional information about the broader spectrum of health from all clinicians involved in an individual's care and can be shared electronically with other authorized health professionals" (WHO 2016). A PHR can be defined as "an electronic application through which individuals can access, manage and share their health information" (Markle 2003). But as said, these definitions are not consistently used in the literature. Thus, to promote consistency, we use the term 'EHR' throughout this protocol, while acknowledging other terms may be used in the reviewed studies. We will include all studies that evaluate patient access independently of how the authors name the institution-based application (e.g. EHR, EMR or PHR). We will use the list of functionalities, described above, to collect information on the type and functionality of the application in detail consistently.

How the intervention might work

There does not exist a uniform theory of how EHR access alone or with additional functionalities might contribute to patient-centred care and related concepts such as patient empowerment or patient participation. However, some qualitative studies and reviews indicate possible mechanisms through which these and other outcomes may be affected.

As defined, EHR access alone gives patients access to their health-related data. This transparency of information may help patients to ensure the accuracy of the stored data (e.g. by identifying missing or erroneous medication data). It may also enable patients to manage their care better (e.g. by allowing a patient to monitor his or her laboratory values) and can improve patient empowerment. It also can increase patient adherence (e.g. regarding medication intake or adherence to guidelines). This in turn can lead to improved clinical outcomes (Otte-Trojel 2014; Mold 2015; Otte-Trojel 2015).

The additional functionalities described above that can be delivered together with EHR access alone may have further or additive effects. Reminders (e.g. reminders to support medicines intake or scheduled examination attendance) may increase effectiveness of presented information, support patient adherence and facilitate shared decision-making. Easy communication with a provider (e.g. by secure e-mail) may enhance interpersonal continuity of care, improve trust and the doctor-patient relationship and improve patient satisfaction and clinical outcomes. Disease-specific health-related information may improve the patient's knowledge and understanding. Also, patient self-documentation may help to detect and decrease adverse events (e.g. by allowing the doctor to monitor medication and related effects better). Finally, providing organizational information may make the patient's navigation through the healthcare system easier, decrease costs and improve service convenience to the patient (Ammenwerth 2012; Otte-Trojel 2014; Mold 2015; Otte-Trojel 2015).

Figure 1 provides a description of how EHR access (alone or with additional functionalities) affects the outcomes.

In contrast, as a possible adverse effect, EHR access may increase feelings of confusion and anxiety when the patient reads clinical information that is unclear to them (Mold 2015). Another challenge is that EHR access with or without additional functionality, like many other eHealth solutions, is created for "people like me: " they may only address the needs of "well-educated and well to-do [wealthy] users rather than the needs of the most disadvantaged in society (the disempowered, disengaged and disconnected" (Showell 2013). For example, a study on users of a patient portal in Kaiser Permanente Georgia showed that portal users were significantly more likely to be white than black and have a higher level of education (Roblin 2009).

Thus, different levels in access and in proficiency in the use of IT, but also different levels in health literacy to interpret appropriately the content provided in the EHR, may influence the frequency of use and the potential benefits from access to EHR. Education or socioeconomic status, therefore, might have an influence on the benefit of EHR access (Graetz 2016). In addition, physical and

mental disabilities might also restrict access and use. All the above indicate that EHR access might have the potential to widen health disparities (i.e. make health inequities worse). It also seems likely that people with chronic conditions who use healthcare services more frequently and where long-term and regular monitoring of the disease is an issue might be a group which profits more than people who only have occasional contact with the healthcare system (Riippa 2014).

Any benefits obtained from EHR access are also closely linked to the amount of data that are made accessible. National EHR systems normally first need to be populated with patient data and this requires time. Institution-based EHR systems, in contrast, normally allow immediate access to health-related data that has already been in the EHR system for some time. We would not expect that an impact evaluation of EHR access is conducted and published when the EHR does not yet include some health-related data for the majority of targeted patients; still, we will examine this. Thus, in this review, we will carefully extract information on how much data for how many patients are made available in the EHR. We will exclude studies where no data are available in the EHR for a majority of targeted patients. To check this, we will verify that the EHR comprises data for at least 20% of the intended target group.

This review will examine EHR access as offered by a healthcare provider. Whether this offer is accepted and used by the patients or not also depends on the usability of the interface that is offered to the patient. Thus, the review will also extract information on features of the EHR, including any reported usability issues.

EHR access differs from earlier attempts to give patients paper copies of their patient records in several ways. First, EHR access is possible via the Internet and thus independent of place (as Internet access is ubiquitous) and time (Internet access is possible 24 hours a day/7 days a week). Second, EHR access is provided automatically to the patient, while providing paper-based copies may involve additional workload for the provider. Third, EHR access can be combined with additional functionalities, thus holding potential to be tailored to patients' needs and to help promote patient-centred care.

Why it is important to do this review

Currently, there is insufficient evidence regarding the effects of providing EHR access alone or with additional functionalities to patients. Thus, healthcare providers do not know whether it is worthwhile to invest in providing EHR access alone or with additional functionalities to their patients or not. Also, patients do not know which effects they can expect when using EHR access alone or with additional functionalities. It is especially unclear which effects and adverse effects EHR access alone or with additional functionalities may have and which group of patients may benefit from it. Also, it is not sufficiently clear whether providing EHR access only already has beneficial effects, or whether this access needs to be supplemented with additional functionalities to be effective.

The impact of providing patients with EHR access alone or with additional functionalities has not been addressed, to our knowledge, by Cochrane Reviews; however, there are a number of Cochrane Reviews on related topics (Murray 2005; Nasser 2010; Adoun 2011; Boyle 2014; Gonçalves Bradley 2015; Goyder 2015). Goyder 2015 reviewed clinical communication between healthcare professionals focused on e-mail communication as the intervention; however, this is not related to EHR access. Murray 2005 reviewed Interactive Health Communication Applications for people with chronic disease focusing on information packages for patients as the intervention; this is also not related to EHR access. Adoun 2011 reviewed promoting sexual and reproductive health and preventing HIV infection; however, they focused on providing promotional and behavioural information on sexual health via Internet/mobile tools, rather than providing EHR access. Boyle 2014 reviewed the use of EHRs to support smoking cessation, focusing on documentation and monitoring of tobacco status and cessation assistance as the intervention. This compares with the current review which will assess access to EHR and its effects on outcomes, but is restricted to smoking-related data. Nasser 2010 reviewed patient record systems focusing on the impact of electronic patient records in dental practice. They compared paper-based records with electronic records, and patient-held records with practice-held records. However, EHR access to practice-held records, which is the scope of our review, was not analyzed in more detail. In summary, there is no Cochrane Review with a specific focus on the effects of patient access to an EHR. Consequently, there is a gap in evidence regarding the question that this review seeks to answer.

As well as Cochrane Reviews, there currently exist a number of related systematic reviews on the effects of EHR access alone or with additional functionalities (Ammenwerth 2012; Goldzweig 2013; Davis Giardina 2014; Otte-Trojel 2014; Irizarry 2015; Mold 2015).

Ammenwerth 2012 identified four controlled studies on EHR access alone or with additional functionalities (three RCTs, one cohort study). There was insufficient evidence to determine the effects of the intervention on any specific outcome. However, there were indications of better patient adherence and lower resource consumption. They did not compare the effects of providing EHR access alone with the effects of providing EHR access with additional functionalities.

Goldzweig 2013 found 14 RCTs on EHR access alone or with additional functionalities. They found mixed or unclear evidence regarding patient satisfaction, patient outcomes, utilization and efficiency. They provided a structured list of available additional functionalities besides EHR access, but did not compare the effects of providing EHR access alone with the effects of providing EHR access with additional functionalities.

Davis Giardina 2014 found 20 randomized controlled trials

(RCTs) on the impact of EHR access alone. Outcomes were equivocal with respect to effectiveness (e.g. physical health outcomes, psychosocial health outcomes, health behaviour), patient-centeredness (e.g. patient satisfaction, patient involvement in care) and efficiency. This review did not focus only on EHR, but also on paper-based records and patient-held records. It also did not describe the intervention in a structured way.

Otte-Trojel 2014 located 32 evaluation studies on EHR access alone or with additional functionalities (18 RCTs, 11 observational studies, three qualitative studies, etc.). The larger number of RCTs comes from the fact that they also included studies where the intervention was only one part of a more multi-component intervention (e.g. a disease-management programme) or where it only offered specific communication functionalities without EHR access. The realist review identified possible effects on several outcomes, including patient empowerment and health resource consumption.

Irizarry 2015 reviewed EHR access alone or with additional functionalities in general. They included all types of studies (including descriptive and qualitative studies). Their review found 120 studies and summarized their findings with regard to adoption by patients, provider endorsement, health literacy of the patients, usability of the user interface, and offered functionalities. This paper did not systematically review the effect of EHR access, but provided a narrative review of success criteria.

Mold 2015 found 17 controlled studies on the impact of EHR access alone or with additional functionalities in primary care. They found that it led to improved satisfaction, improved self-care, better communication and engagement with clinicians, and found variable effects on face-to-face contacts. They focused their review on primary care only and did not distinguish between EHR access alone or with additional functionalities.

Summarizing, available reviews do not present a clear picture of the effects of EHR access alone or with additional functionalities to enable evidence-based decisions on their use to be made.

OBJECTIVES

To assess the effects of providing access to electronic health records (EHR) alone or with additional functionalities to adult patients on a range of patient, patient-provider and health resource consumption outcomes.

The secondary objective is to compare the effects of providing EHR access alone, compared with EHR access with additional functionalities, to adult patients and to assess whether the effects differ among patient groups according to age, educational level or different status of disease (chronic or acute).

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs and cluster RCTs on the effects of providing adult patients with access to an EHR.

Types of participants

All adult patients (aged 18 years and above) who are given access to their EHR by a healthcare provider will be included.

We will include EHR access independent of the medical condition of the patient.

We will exclude patients under 18 years of age, as the effects of patient-centred care on children and their parents are expected to be different to adult patients.

We will exclude studies where relatives or informal carers are mentioned as a major target group of the intervention.

Types of interventions

We will include studies assessing the effects of access to the EHR, alone or with additional functionalities.

'Access to EHR alone' will cover EHR functionality #1 from the following list, 'access to EHR with additional functionalities' will covers at least one of the functionalities #2 to #7.

1. Access: access to health-related data (e.g. viewing test results, visit notes, information about condition or treatment, medical history) (this will be the focus of this review).
2. Remind: preventive health maintenance reminders (e.g. for immunization, mammography, screening tests).
3. Request: transactional services (e.g. repeat prescription, appointment booking, referral requests).
4. Communicate: bilateral messaging service (e.g. secure messaging for non-urgent medical questions and administrative concerns).
5. Share: patient self-documentation (e.g. manage medication list, approve content of clinical notes, upload blood pressure measurements, personal diary).
6. Manage disease: individualized disease management functions (e.g. individual guidelines, generation of an individual care plan).
7. Educate: general educational clinical information.

We will include studies independent of the location of the study, that is, which type of healthcare organization is offering the EHR access (e.g. primary care, secondary care, national level).

We will only include studies where EHR access is provided via an electronic interface and independent of a given location (this means access is typically provided via an Internet-based application and is not only provided at dedicated computer terminals at the hospital or doctor's surgery).

We will include EHR access in the context of disease management programmes or other multi-component interventions if it is pos-

sible to isolate and report the effects of the EHR access interventions from the larger intervention.

We will include the following comparisons:

1. EHR access alone or with additional functionalities with usual care versus usual care only.
2. EHR access alone versus EHR access with additional functionalities.

Summarizing, we will include the following:

1. patients who can access their own EHR (anytime and anywhere);
2. patient who is the main user (i.e. not a healthcare professional or carer or relative of the patient);
3. record that contains any type of patient-specific health-related data (both longitudinal health-related data and episodic data such as data related to a pregnancy);
4. record that is offered by any healthcare provider (e.g. primary care physician, healthcare organization, national healthcare system).

We will exclude the following when:

1. no function for EHR access is offered to the patient;
2. there is only access to paper-based records (e.g. print-outs);
3. there is access only to general educational information;
4. access not possible from the patient's home;
5. access not possible for the majority of patients due to missing data in the EHR (e.g. the EHR contains patients' data for less than 20% of the targeted patient population).

Types of outcome measures

Primary outcomes

We expect that EHR access alone or with additional functionalities may impact on the following outcomes relevant to decision-makers and thus include them as primary outcomes.

1. Patient knowledge and understanding (e.g. disease-related knowledge).
2. Patient empowerment* (e.g. patient autonomy, self-management, self-efficacy, patient participation).
3. Patient adherence (e.g. attendance rates, treatment adherence, active reduction of risk factors).
4. Patient satisfaction with care (e.g. with treatment, with process, with patient-provider relationship, acceptability of the intervention).
5. Adverse events (e.g. patient anxiety due to unclear information, or delay in treatment due to misleading information).

*The category 'patient empowerment' covers all outcomes related to this concept. As no uniform theory of patient-centeredness and patient empowerment exists, this category is meant to include various concepts such as patient autonomy, self-management, self-efficacy or patient participation.

The outcomes reported in the 'Summary of findings' table will be all primary outcomes: patient knowledge and understanding, patient empowerment, patient adherence, patient satisfaction with care, and adverse events.

Secondary outcomes

1. Health-related quality of life.
2. Health-related outcomes.
3. Psychosocial health outcomes (e.g. anxiety, confusion, depression, worry).
4. Health resource consumption (e.g. number of phone calls, number of visits, number of hospitalizations, provider workload, visit length).
5. Patient-provider communication (e.g. quality and quantity of communication).

Timing of outcome assessment depends on how often EHR access is used and on the observed outcome. It is thus not appropriate to define a general timing of outcome assessment. However, we define that EHR access must have been offered for at least one month before data are collected. If repeated measurements were done, we will limit outcome measurement to only one time interval considered most relevant for the endpoint (this is typically the outcome measurement taken at longest follow-up).

Two authors (EA, PS) will independently assign the outcomes reported in each included study to the review's outcome categories and resolve any differences in categorization, if they occur, by the involvement of a third author (AH).

If a study contributes multiple times to the same outcome category (e.g. by using different instruments), we will proceed as follows.

1. If the publication authors selected one of the outcomes as primary outcome, we will take this outcome for the review.
2. Where no primary outcome was defined by the study authors, we will take the outcome specified in the sample size calculation.
3. If there were no sample size calculations in the study, we will decide which outcome within a category is most important for the patient also taking into consideration when similar outcomes have been measured in other trials to include comparable outcomes. Therefore, we will provide an overview with all outcome measures used in all included studies and how they were measured (e.g. scales). Two authors (EA, PS) will independently make these decisions and resolve any differences in categorization, if they occur, by the involvement of a third author (AH).

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

1. Cochrane Central Register of Controlled Trials (CENTRAL, the Cochrane Library) (2000 to latest issue);
2. MEDLINE (OvidSP) (2000 to present);
3. Embase (OvidSP) (2000 to present);
4. PsycINFO (OvidSP) (2000 to present);
5. CINAHL (EBSCO) (2000 to present);
6. SCOPUS (2000 to present).

We present a first outline of the search strategy for MEDLINE in Appendix 1.

We will tailor strategies to other databases and report them in the review.

We will limit searches to studies to the year 2000 and after, because EHR access via patient portal was not available before that time (Irizarry 2015).

There will be no language restrictions.

Searching other resources

We will search a range of grey literature sources as well as proceedings of the following conferences from 2000 to present:

1. MedInfo conference;
2. Medical Informatics Europe conference;
3. AMIA annual conference.

To be sure also to identify studies that do not use the chosen search terms in title or abstract, or are not indexed at all in electronic libraries, we will handsearch the following journals from 2000 to present:

1. *Journal of the American Medical Informatics Association*;
2. *International Journal of Medical Informatics*;
3. *Applied Clinical Informatics*;
4. *Journal of Medical Internet Research*;
5. *BMC Medical Informatics and Decision Making*;
6. *Telemedicine and eHealth*.

We will contact experts in the field (using our contacts in International Medical Informatics Association, European Federation for Medical informatics and American Medical Informatics Association) and authors of included studies for advice as to other relevant studies.

We will also search reference lists of identified relevant studies.

We will search reference lists of systematic reviews on access to EHRs and patient portals.

We will also search online trial registers (ClinicalTrials.gov (clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) portal (www.who.int/ictrp/en/)) for ongoing and recently completed studies.

Data collection and analysis

Selection of studies

Two authors will independently screen all titles and abstracts identified from searches to determine whether they meet the inclusion criteria. We will retrieve in full text any papers identified as potentially relevant by at least one author. Two authors will independently screen full-text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third author if necessary to reach consensus.

We will list all potentially relevant papers excluded from the review at this stage as excluded studies, with reasons provided in the 'Characteristics of excluded studies' table. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and selection process in an adapted PRISMA flow chart (Liberati 2009).

Data extraction and management

Two authors (EA, PS) will extract data independently from included studies, using a predefined and piloted data collection form. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third author (AH) where necessary. We will develop and pilot the data extraction form using the Cochrane Consumers and Communication Group Data Extraction Template (available at: cccrg.cochrane.org/author-resources).

Data to be extracted will include the following items:

1. details of the study (aim of intervention, study design, number of arms, funding source, declaration of interest, ethical approval);
2. risk of bias assessment;
3. study characteristics - participants (description of target group of intervention, location, setting, recruitment, inclusion/exclusion criteria, age, gender, ethnicity, numbers of participants);
4. study characteristics - intervention (name, aims, owner, location, setting, functionality - free text and according to our classification of functions, usage patterns, intervention fidelity - i.e. whether EHR access was usable, whether it was used as intended and which was made available in the EHR for how many patients), training, skills and experience of providers or patients or both;
5. study characteristics - outcomes and comparison groups (methods and timing of assessing primary and secondary outcomes, scales and instruments used, adverse events, methods for follow-up of non-respondents);
6. data and results (data on primary and secondary outcomes).

One author will enter all extracted data into Review Manager (RevMan 2014), and a second author will check them for accuracy against the data extraction sheets.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included studies in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and the guidelines of the Cochrane Consumers and Communication Review Group (CCCG 2014), which recommends the explicit reporting of the following individual elements for RCTs:

1. random sequence generation;
2. allocation sequence concealment;
3. blinding (participants, personnel);
4. blinding (outcome assessment);
5. completeness of outcome data;
6. selective outcome reporting;
7. other sources of bias such as comparability of intervention and control group at baseline.

We will consider blinding separately for different outcomes where appropriate (e.g. blinding may have the potential to affect subjective versus objective outcome measures differently). We will judge each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provide a quote from the study report and a justification for our judgement for each item in the risk of bias table.

We will exclude studies that are scored as high risk of bias for random sequence generation as they are not RCTs and based on growing empirical evidence that this factor is a particularly important potential source of bias (Higgins 2011). For studies scored as high or unclear risk of bias for allocation concealment, we will conduct sensitivity analysis by either including or excluding them. For judgement about high or unclear risk of bias, we will use the criteria in Section 8.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

For cluster-RCTs, we will also assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants.

In all cases, two authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required.

We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect

For dichotomous outcomes, we will analyze data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI).

For continuous measures, we will analyze data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results.

If more than one study measures the same outcome using different tools, we will calculate the standardized mean difference (SMD) and 95% CI.

Unit of analysis issues

If cluster-RCTs are included, we will check for unit-of-analysis errors. If there are errors, and sufficient information is available, we will reanalyze the data using the appropriate unit of analysis, by taking account of the intra-cluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute results using estimates from external sources. If it not possible to obtain sufficient information to reanalyze the data, we will report effect estimates and annotate unit-of-analysis error.

Dealing with missing data

We will attempt to contact study authors to obtain missing data (participant, outcome or summary data). For participant data, we will, where possible, conduct analysis on an intention-to-treat basis; otherwise data will be analyzed as reported. We will report on the levels of loss to follow-up and assess this as a source of potential bias.

For missing outcome or summary data, we will carry out an available-case analysis and consider the implications of the missing data in the review 'Discussion'.

Assessment of heterogeneity

Where studies are considered similar enough (based on consideration of participants, settings, intervention, comparison and outcome measure) to allow pooling of data using meta-analysis, we will assess the degree of heterogeneity by visual inspection of forest plots and by examining the Chi^2 test for heterogeneity. Heterogeneity will be quantified using the I^2 statistic. An I^2 value of 50% or more will be considered to represent substantial levels of heterogeneity, but this value will be interpreted considering the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi^2 test (Higgins 2011).

Where we detect substantial clinical, methodological or statistical heterogeneity across included studies we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event, we will attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of populations, intervention and

comparison features, methodological features or healthcare setting to explore differences in intervention effects.

When few trials are included in a meta-analysis, the Chi² test has little power to detect heterogeneity. Therefore, a non-significant result should not necessarily be interpreted as evidence of no heterogeneity and should be instead interpreted with care.

Assessment of reporting biases

We will assess reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies that indicate positive findings are identified for inclusion), and if information that we obtain from contacting experts and authors or studies suggests that there are relevant unpublished studies.

If we identify sufficient studies (at least 10) for inclusion in the review, we will construct a funnel plot to investigate small-study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice in Higgins 2011, and considering that there may be several reasons for funnel plot asymmetry when interpreting the results.

Data synthesis

We will decide whether to meta-analyze data based on whether the interventions in the included trials are similar enough in terms of participants, settings, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in the population and the functionality of the interventions as well as comparisons and settings of included studies, we will use a random-effects model for meta-analysis.

If we are unable to pool the data statistically using meta-analysis, we will conduct a narrative synthesis of results. We will present the major outcomes and results, organized by intervention functionalities and aims of interventions. Depending on the assembled research, we may also explore the possibility of organizing the data by population. Within the data categories, we will explore the main comparisons of the review:

1. EHR access alone or with additional functionalities with usual care versus usual care only;
2. EHR access alone versus EHR access with additional functionalities.

If EHR access is part of a multi-component intervention (e.g. disease management programme), comparisons will only be done if the effects of the EHR intervention can be isolated from the multi-component intervention.

Where studies compare more than one intervention, we will compare each separately to control; and with one another.

Subgroup analysis and investigation of heterogeneity

Where sufficient studies exist, we will undertake the following a priori defined subgroup analyses:

1. patients with high (more than 10 years) versus low (10 years or less) education levels. Educational level may influence computer literacy and health literacy and these in turn may influence intensity of intervention usage;
2. patients with chronic diseases versus patients without chronic diseases or if the latter is not reported versus all patients. Chronic patients may use healthcare services more frequently. Where long-term and regular monitoring of the disease is required, patients with chronic diseases may benefit more from the intervention than other patients;
3. age groups (e.g. all versus 65 years and older). Age may influence computer literacy and consequently the uptake, acceptability and intensity of the usage of the intervention.

If a statistical subgroup analysis is not possible, we will narratively explore the relationships by summarizing the results in text or tables according to the subgroups defined above.

Sensitivity analysis

For studies scored as high or unclear risk of bias for allocation concealment, we will conduct sensitivity analysis by rerunning meta-analyses either including or excluding such studies.

If cluster-randomized studies are included and we have corrected for the ICC by using ICC estimates from other studies, we will compare results based on imputed data by sensitivity analyses for the ICC coefficient using minimal and maximal values for the ICC imputed from external sources.

'Summary of findings' table

We will prepare a 'Summary of findings' table to present the results of meta-analysis, based on the methods described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We will present the results of meta-analysis for the major comparisons of the review, for each of the major primary outcomes, including potential adverse events, as outlined in the Types of outcome measures section. We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE system to rank the quality of the evidence using GRADEprofiler (GRADEpro) software (Schünemann 2011).

If meta-analysis is not possible, we will present results in a narrative 'Summary of findings' table format, such as that used by Chan 2011.

Ensuring relevance to decisions in health care

This review should inform real world decisions about whether healthcare organizations should offer EHR access to their patients. The relevant target readership of the review are thus Chief Information Managers and Chief Executive Officers of healthcare organizations (such as hospitals). However, patients will also be

interested to understand whether EHRs are effective. to inform their decisions about whether to take up EHR access, if offered to them by a healthcare provider. In addition, administrators at local government bodies may be interested, as far as they are concerned with funding of healthcare providers.

We plan to form an international advisory board of representatives from healthcare organizations, patient groups and researchers. We will use our contacts to select members of the advisory board. This advisory board will be contacted by e-mail or telephone conference (or both) to discuss issues of study planning, paper selection and result interpretation.

The protocol and review will receive feedback from at least one consumer referee in addition to a content expert as part of Cochrane Consumers and Communication's standard editorial processes.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1. exp medical records systems computerized/
2. exp health records personal/
3. (personal adj (health record* or medical record*)).ti,ab,kf.
4. ((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)).ti,ab,kf.
5. ((web or internet or computer*) adj3 (health record* or medical record* or personal record* or patient record*)).ti,ab,kf.
6. (ehr? or phr? or ephr? or emr? or paehr?).ti,ab,kf.
7. (patient adj2 portal*).ti,ab,kf.
8. or/1-7
9. access*.mp.
10. 8 and 9
11. patient access to records/
12. ((access* adj5 record*) and patient*).mp.
13. ((access* adj3 patient*) and record*).mp.
14. or/11-13
15. (internet or web* or computer* or electronic* or online or on-line or digital* or portal*).mp.
16. 14 and 15
17. 10 or 16
18. randomized controlled trial.pt.
19. controlled clinical trial.pt.
20. randomized.ab.
21. placebo.ab.
22. drug therapy.fs.
23. randomly.ab.
24. trial.ab.
25. groups.ab.
26. or/18-25
27. 17 and 26

CONTRIBUTIONS OF AUTHORS

EA is the review's guarantor.

The protocol was jointly developed by EA and PI and reviewed by SL, AH and GM.

In the review, EA will co-ordinate the literature search. EA and PS will preselect studies and AH will resolve any disagreements. EA, PS and AH will extract data. PS, with the support of GM and SL, will co-ordinate data synthesis. EA and PS will co-ordinate writing of the review, with all authors contributing.

DECLARATIONS OF INTEREST

EA, AH and PS have published a systematic review on patient portals (Ammenwerth 2012). SL and GM have declared no conflicts of interest.

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- No sources of support supplied

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